

INTE00004-100  
SERIAL NO.: 10/032,311

PATENT  
FILED: December 21, 2001

### REMARKS

Claims 1-49 were pending in the application and subject to restriction. Claims 9-49 were withdrawn as drawn to a non-elected invention. Claims 3, 4, 14, 16, 17, and 36 have been canceled without prejudice. Claims 1, 5, 6, 9, 18, 19, 27, 33, 42, 43, 45, and 47 have been amended. Claims 9, 27, 33, 42, 43, 45, and 47 have been amended to depend on claim 1. Upon entry of this amendment, claims 1, 2, 5-8 will be pending. No new matter has been added.

#### Linking Claim

As stated by the Office at page 3 of the Restriction Requirement mailed July 22, 2004, the present application contains linking claims. Specifically, the claims of Group I, presently under consideration, comprise at least one such claim (*e.g.* claim 1). Applicants respectfully acknowledge, as pointed out by the Office at page 3 of the Restriction Requirement, that upon allowance of claim 1 of the presently elected invention, the Restriction Requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application.

As also observed in the Restriction Requirement (page 4), the Office stated that process (method) claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. § 821.04 and that in the event of rejoinder the Restriction Requirement will be withdrawn and the claims dependent on the product claim will be examined for patentability. Accordingly, Applicants have amended claims 27, 33, and 42 to depend on the product claim (claim 1). Applicants have similarly amended claims 9, 43, 45, and 47 to depend from claim 1 and request that it be examined as well.

#### Rejection under 35 U.S.C. § 112

Claims 1-8 were rejected under 35 U.S.C. § 112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Office alleges that the claims

broadly directed toward a lipoparticle of undefined structure comprising a multiple membrane spanning protein of undefined structure. Concerning the membrane spanning protein, the only limitation provided is a negative one that simply specifies that the protein cannot be CD63. However, it fails to provide any further illumination on the structure of the protein. Concerning the lipoparticle, the claims fail to provide any structural limitations. Perusal of the disclosure fails to review any significant teachings that would lead the skilled artisan to any particular structure. Thus the skilled artisan would reasonably conclude that applicants were not in possession of the claimed invention at the time of filing.

(Office Action, page 4). Applicants traverse this rejection.

Applicants respectfully disagree that the structure of the lipoparticle is undefined. Lipoparticle is defined in the specification. Nonetheless, in order to further prosecution Applicants have amended claim 1 to recite, "An isolated lipoparticle comprising an enveloped virus vector, said lipoparticle further comprising a multiple membrane spanning protein wherein said protein is not CD63." Support for this amendment can be found throughout the specification as filed, for example, at page 18, beginning at line 6, where the lipoparticle comprising an enveloped virus is described.

Regardless, Applicants have sufficiently described the invention. The M.P.E.P states:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus

(M.P.E.P. § 2163). Applicants have amply demonstrated possession of the claimed invention. Applicants have described a representative number of species of lipoparticles comprising enveloped virus vectors to exhibit possession of the invention. The Applicants describe the construction and use of lipoparticles comprising enveloped virus vectors in detail sufficient to

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demonstrate to one of skill in the art that the Applicants were in possession of the claimed invention. Indeed, the specification discloses the preparation of two types of lipoparticles comprising divergent enveloped virus vectors, one derived from HIV—the cause of infectious disease in humans—and one derived from MLV—the cause of cancer in mice. The lipoparticle presently claimed, thus, is not limited to characteristics derived from one type of enveloped virus.

The specification as filed further discloses additional types of enveloped viruses for use in the lipoparticle of the present invention. For example, at page 90, beginning at line 20, the specification instructs the skilled artisan regarding enveloped virus selection. For example, vesicular stomatitis virus, Rous-Sarcoma virus, murine leukemia virus, human immunodeficiency virus, and rabies virus, in addition to the enveloped viruses described elsewhere in the specification, are set forth.

The Office also alleges that the specification as filed does not provide adequate written description for the membrane spanning protein presently claimed, and that the protein has an undefined structure and that the only limitation to the protein is that it is not CD63. Applicants have sufficiently described a representative number of species of multiple membrane spanning proteins to exhibit possession of the invention. Applicants respectfully turn the Office's attention to page 59, beginning at line 7, where a multiple membrane spanning protein is described as a polypeptide that spans the cell membrane at least twice. Thus, contrary to the Office' assertion the protein is not without structure.

Moreover, one of skill in the art would reasonably conclude that Applicants were in possession of a lipoparticle comprising an enveloped virus vector further comprising any multiple membrane spanning protein at the time the present application was filed. The specification discloses the preparation of lipoparticles comprising multiple membrane spanning proteins. For example, numerous divergent multiple membrane spanning proteins are described at page 62, beginning at line 5, of the specification. The specification discloses, for example, membrane proteins such as G-protein coupled receptors, mu-opioid receptors, as well as transporters (proteins that transport molecules such as, but not limited to, amino acids or carbohydrates, across a membrane), ion channels, and the like. The specification also discloses

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lipoparticles comprising multiple membrane spanning proteins, such as CXCR4, CCR5, and MCAT-1. For example, the specification discloses a lipoparticle comprising the MLV receptor protein MCAT-1 (see, page 63, beginning at line 18) and lipoparticles comprising CXCR4 or CCR5 (see, Example 3, page 78, beginning at line 15).

Accordingly, the skilled artisan would know that Applicants were in possession of the claimed invention at the time of filing. Applicants have demonstrated possession by describing lipoparticles comprising a variety of enveloped virus vectors and multiple membrane spanning proteins. Thus, for the reasons set forth above, Applicants respectfully submit that the specification as filed provides sufficient written description for the claims as presently amended, and, therefore, respectfully request reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. § 112, first paragraph.

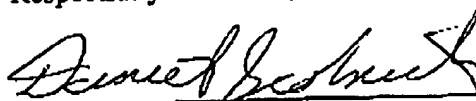
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### Conclusion

Applicants believe the claims are in condition for allowance. An early Notice of Allowance is therefore earnestly solicited. Applicants invite the Examiner to contact the undersigned at (215) 665-6928 to clarify any unresolved issues raised by this response.

Respectfully submitted,



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